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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,759	09/08/2003	David Lewis	48924-01030	1172

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EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/657,759	LEWIS ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-17,19-21 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 6-17, 19-21, 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of amendments and Remarks filed on 07/16/07. Claims 1, 17 and 21 have been amended. No claims have been cancelled or newly added. Accordingly, claims **1, 6-17, 19-21, 24-26** remain pending and under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims **1, 6-17, 19-21, 24-26** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 17 and 21 have been amended to include the limitations "outwardly" (claim 1) and "to reduce the compression of the gasket and thereby reduce the release of gasket components" (claims 1, 17 and 21). The said limitations do not have support in the specification.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 6-16 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WU et al (WO 0078286) in view of Lasserre et al (6,296,156).

Wu teaches a medicinal aerosol steroid formulation product with enhanced stability. The steroid is a 20-ketosteroid having an OH group at the C-17 or C-21 position and the aerosol container has a **non-metal interior surface which has been found to reduce chemical degradation of such steroids** (see abstract). Wu also discloses that steroids, especially 20-ketosteroids, are subject to enhanced chemical degradation, when stored in contact with a metal container (particularly the metal oxide e.g., AL_2O_3 layer that forms on the interior surface of the container) (see page 3). The preferred 20-ketosteroids include budesonide, triamcinolone acetonide, dexamethasone and betamethasone. The most preferred type of container is a conventional aluminum (or aluminum alloy) aerosol canister, the interior surface of which is coated with an inert material, such as spray-coated, baked epoxy-phenolic lacquer. The internal surfaces of metal valve components in contact with the formulation are similarly coated with an inert material. Another preferred coating for the inside of the container is perfluoroethylenepropylene (FEP). The coating is preferably used on all of the metal valve components in contact with the formulation, including the inside and outside of the metering chamber, inside and outside of the bottle emptier and the inside and outside of the valve stem (see page 4). The device used is a **metered dose** inhaler (MDI). Wu lacks specific disclosure on the rolled neck canister.

Lasserre et al teaches a mounting device for mounting a valve on a container and a dispenser containing a product under pressure fitted with such a mounting device. The inner surface of the cup which comes in contact with the product is coated with a lacquer or some other inert thermoplastic layer (col. 1, lines 63-65). The container containing a product, particularly a liquid, placed under **pressure** by a conventional propellant, to be dispensed by actuation of the dispensing valve. The open end of the container is formed by a neck, the said neck having a profile capable of engaging with a portion formed on the said external first mounting means. The neck of the container may be **rolled outwards** with respect to the central axis of the container or alternatively may be rolled inwards with respect to the axis of the container. The neck of the container has an edge bent towards the central axis of the container (col. 4, lines 1-34). The container may be a one-piece aluminum can. The cup is made of plastic, such as polyacetal (col. 4, lines 63-67).

With regards to limitations of claims 6-7, wherein the valve is washed before crimping of the valve upon the canister, it is noted that such limitation is 1) a process step and typically process steps in a product claim are not given patentable weight. 2) not patentably distinguishable from prior art because ethanol is known to be used for sterilization. Furthermore, washing the valve with ethanol does not does not materially change the device, alter the set up of the device or affect the function of the device.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the teachings of Wu et al on providing a stable aerosol formulation of a 20-ketosteroid by reducing chemical degradation, to have looked in the art for a more specific device with rolled neck to use with the said formulations, as taught by Lasserre et al with a reasonable expectations of successfully preparing, storing and delivering a stable steroid formulation. In other words a combination of the references would have led one of ordinary skilled in the art to the invention as claimed.

Claims 17, 19-21 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WU et al (WO 0078286) in view of Abplanalp et al (6,668,439).

Wu et al, discussed above, teaches a metered dose inhaler device with a non-metal interior surface which has been found to reduce chemical degradation of formulations such as those comprising steroids and is suitable for the storage and delivery of such solution formulations. Wu et al, however, lacks disclosure on specific steps and the rolled neck.

Abplanalp et al discloses an apparatus for forming a double-segment overlapping gasket material for the mounting cup of an aerosol container comprising a punch mounted on a reciprocating ram having a central opening for the body of the mounting cup and a nose portion adapted to extend within the channel portion of the mounting cup (see abstract and col. 3, lines 22-31).

Abplanalp et al also discloses that the dispensing valve, crimped to a mounting cup having a sealing gasket, is normally mounted in a top opening of the container, which opening is defined by a component commonly referred to as the "bead' of the container opening. The mounting cup includes a central pedestal portion for crimping the dispensing valve, a profile portion extending outward from the pedestal portion, which profile portion merges into an upwardly extending body portion, the body portion emerging into a channel portion terminating in a skirt portion (col. 1, lines 31-43 and col. 7, lines 8-27).

It is also disclosed that various types of sealing gaskets are known in the art. One common type of gasket comprises a conventional flat rubber gasket that is placed inside the channel of the mounting cup (col. 1, lines 53-65). The preferred form of the mounting cup, the fold-over sleeve gasket is an ultra low density polyethylene with an added thermoplastic elastomer (col. 4, lines 6-8).

Abplanalp et al teaches that valve assembly includes a mounting **gasket** and an upper **rolled rim** or bead that extends around opening. Folded-over gasket is disposed between bead and the under surface of channel (col. 5, lines 41-55).

With regards to limitations of claims 19 and 21, wherein the valve is washed before crimping of the valve upon the canister, it is noted that such limitation is not patentably distinguishable from prior art because ethanol, is known to be used for sterilization. Furthermore, washing the valve with ethanol does not materially change the device, alter the set up of the device or affect the function of the device.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the teachings of Wu et al on providing a stable aerosol formulation of a 20-ketosteroid by reducing chemical degradation stored and delivered by a suitable metered dose inhaler device, to have looked in the art for a more specific device with rolled neck to use with the said formulations, and for specific steps of mounting the cap and the gasket as taught by Abplanalp et al with a reasonable expectations of successfully preparing, storing and delivering a stable steroid formulation. In other words a combination of the references would have led one of ordinary skilled in the art to the invention as claimed.

Response to Arguments

Applicant's arguments filed 07/16/07 have been fully considered but they are not persuasive.

Applicant's main argument is that Wu et al, Lasserre et al and Abplanalp et al are solving the problem of chemical stability of the formulation differently than the instant invention is. Applicant argues that the combination of Wu et al and Lasserre et al or Wu et al and Abplanalp et al do not lead one of ordinary skill in the art to the instant invention. This is not persuasive. Firstly claims 1-16 are drawn to a product comprising a solution formulation product. It has been shown that the limitations pertaining to the product have been met by the cited prior at. Wu is clearly teaching the formulation and a canister with a gasket to prevent contact of the formulation with metal component (see page 6, lines 20-26). Secondly, when Wu teaches that formulation should be kept away

from the metal surfaces of the canister, it includes the edges of the neck too. Thus the combined references teach a method of providing a stable formulation. Lasserre et al teaches a similar device which has rolled rim. One of ordinary skill in the art would have been motivated to design the device with rolled neck to insure no contact between solution and the metal edges of the canister or its parts.

Applicant argues that instant claim 1 involves a "metering valve" and not all canister valves are structured the same. It is also argued that the rubber gaskets as claimed contact the formulation in the canister. This is not persuasive because Wu et al disclose a metered dose inhaler and is clearly stated that "a solution gasket 30 is used to further prevent contact of the formulation with metal components", which means that the gasket is in contact with the solution. Lasserre et al is also disclosing a dispensing valve including an actuator.

Applicant directs attention to the results presented in Example 4 and Tables 4 and 5, which demonstrate that stability of the solution of an active medicament stored in cans finished with a rolled neck is greatly improved in comparison with cut edge cans. This is not persuasive because 1) Applicant's comparison of the rolled neck to cut edge does not overcome the rejection because it has been shown that the prior art has recognized the advantage of the rolled neck in improving stability of the formulations. Thus the argument is not that rolled neck improves stability, but that Wu has a different solution to the stability problem. It is also noted that Table 4 shows percent recovery of various salts of budesonide from start to 12 months stored in an epoxy-phenol

lacquered rolled neck can. Table 5 shows a slight improvement in a rolled in compared to cut edge, however there is no data comparing rolled over to cut edge.

Applicant argues that Wu is solving the stability of the solution by coating the inside of the canister. This is correct but not persuasive, because 1) the instant claims also require part or all of the internal surfaces be coated by inert material and the lacquered can is used for data in Table 4. Example 4 reads "the stability of the solution is greatly increased due to two factors: -the different finishing of the can and –the total gasket area exposed to the solution is much lower. Wu discloses both of these steps to improve stability. Furthermore, the figures in the Wu et al reference show that the neck is rolled away and that the gasket keeps the formulation inside the canister and away from any contact with the metal part. This is exactly what the instant Application is claiming. 2) The claims have been rejected under obviousness over Wu et al and Lasserre and it has been shown that Lasserre teaches a device with rolled neck.

Applicant argues that Lasserre does not address the problem related to stability of the solution and does not remedy deficiencies of Wu et al because it discloses ways of mounting a dispensing valve on a container. Additionally it is argued that Lasserre does not teach a rolled rim in the abstract, but rather teaches a rolled rim that mates in a corresponding U-shaped receiving portion of the cup. Applicant then concludes that Lasserre can not be combined with Wu. This is not persuasive because it has been shown that Wu teaches a metered dose device concerned with stability of the solution formulation and while not disclosed in words, the figures show a rolled neck. Wu specifically teaches that the aim is to reduce or eliminate contact between solution and

metal. It would have been obvious to one of ordinary skill in the art that the cut edge of a metal container needs to be kept away from coming to contact with the solution. Lasserre teaches rolled neck. The specific steps related to the process claims are not given patentable weight in a product claim. It has been shown that the combination of Wu and Lasserre meet all the limitations of the product claims 1 and 6-16.

Applicant argues that Abplanalp et al refers to valve mounting assemblies for aerosol containers and "there is nothing in Abplanalp which can cure the basic deficiencies of Wu and Lasserre". This is not persuasive because it has been shown that Wu et al teaches a process for making a chemically stable aerosol solution formulation product. Wu lacks the specific disclosure of rolled neck. Claim 17 requires the step of "forming a rolled neck" and claim 21 requires a step of "providing a canister with rolled neck". Abplanalp teaches both steps thus curing the deficiencies in Wu.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian

September 20, 2007

Johann R. Richter

Supervisory Patent Examiner

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